EXHIBIT 25

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 8:20-cv-1320-TDC

DECLARATION OF HILARY K. PERKINS

I, HILARY K. PERKINS, declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am a Trial Attorney at the U.S. Department of Justice, Consumer Protection Branch, with offices at 450 5th Street, N.W., Washington, D.C. 20530, counsel for Defendants in the above-captioned action. I submit this declaration in support of Defendants' Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction.

2. Attached as Exhibit 10 is a true and correct copy of the United States Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategies: Modifications and Revisions, Guidance for Industry, dated July 2019.

3. Attached as Exhibit 11 is a true and correct copy of FDA's Memorandum approving a New Drug Application (NDA) for Mifeprex, dated September 28, 2000, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.,* Case No. 1:17-cv-493 (D. Hawaii).

4. Attached as Exhibit 12 is a true and correct copy of FDA's approved labeling text for Mifeprex, dated September 28, 2000, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

5. Attached as Exhibit 13 is a true and correct copy of FDA's Final Deemed Risk Evaluation and Mitigation Strategy (REMS) Review for Mifeprex, dated June 3, 2011, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

6. Attached as Exhibit 14 is a true and correct copy of FDA's Final REMS Review for Mifeprex, dated October 10, 2013, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

7. Attached as Exhibit 15 is a true and correct copy of FDA's Cross-Discipline Team Leader Review for Mifeprex, dated March 29, 2016, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

8. Attached as Exhibit 16 is a true and correct copy of FDA's Summary Review for Mifeprex, dated March 29, 2016, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

9. Attached as Exhibit 17 is a true and correct copy of FDA's Labeling Comments Review for Mifeprex, dated March 29, 2016, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

10. Attached as Exhibit 18 is a true and correct copy of FDA's REMS Modification Review for Mifeprex, dated March 29, 2016, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

11. Attached as Exhibit 19 is a true and correct copy of FDA's Clinical Review for Mifeprex, dated March 29, 2016, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

12. Attached as Exhibit 20 is a true and correct copy of FDA's approval letter for the generic version of Mifeprex, dated April 11, 2019.

13. Attached as Exhibit 21 is a true and correct copy of the Single-Shared Mifepristone REMS Program, dated April 11, 2019.

14. Attached as Exhibit 22 is a true and correct copy of the drug product label for Korlym, dated February 17, 2012, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

15. Attached as Exhibit 23 is a true and correct copy of FDA's Risk Management Review for Korlym, dated January 27, 2012, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

16. Attached as Exhibit 24 is a true and correct copy of FDA's Summary Review for Korlym, dated February 17, 2012, which was part of the administrative record in *Chelius v. United States Food & Drug Admin.*, Case No. 1:17-cv-493 (D. Hawaii).

I declare under penalty of perjury that the foregoing is true and correct. Executed on June 10, 2020.

Hilary K. Perkins